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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,241	12/15/2003	Gil U. Lee	NC 95, 996	2269

26384 7590 04/14/2005

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EXAMINER

COUNTS, GARY W

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 04/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/734,241

Applicant(s)

LEE ET AL.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 16, 26-35 and 37-45 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 26-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 and 37-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Status of the claims

The amendment filed January 25, 2005 is acknowledged and has been entered. Claims 17-25 and 36 have been cancelled. Claims 15, 16, 26-35 and 37-45 remain. Claims 15 and 26-35 are withdrawn as being directed to a non-elected invention.

Election/Restrictions

1. Applicant's election of Group II, Claims 16 and 36-45 in the reply filed on January 25, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 16, 37, 44 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Sosnowski et al (US 6,051,380).

Sosnowski et al disclose the detection of analytes (abstract). Sosnowski et al disclose contacting a sample containing the analyte (test solution) to a device.

Sosnowski et al disclose that the device contains a permeation layer with selective

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diffusion properties (col 25, lines 13-15). Sosnowski et al disclose that this permeation layer should have a pore limit property which inhibits larger binding entities, reactants and analytes from passing through to the micro-electrode surface (col 25, lines 26-33). Sosnowski et al disclose that the permeation layer can be a porous membrane (col 25, line 45 and col 27, lines 51-53). Sosnowski et al disclose that the outer surface of the membrane is derivatized with chemical functional groups (membrane surface modifiers) (col 27, lines 52-53). Sosnowski et al discloses that these chemical functional groups bind to specific binding entities (col 28) and that these specific binding entities have affinity for another molecule (col 9). Sosnowski et al disclose that detection of binding reactions can be achieved by using labeled reporter groups and that these labels can be conjugated to DNA or antibodies (binding ligands) (col 35, lines 35-41). Sosnowski et al disclose that the labels can be fluorescent, chemiluminescent and enzymatic (col 35, lines 35-41). Sosnowski et al disclose using an imaging or scanning detector system to detect labels (col 8). Sosnowski et al disclose that the ideal pore limit is from 2nm to 10 nm (col 27, lines 37-38). Sosnowski et al disclose that the pores allow a solvent to pass through (col 25, lines 21-24). Sosnowski et al disclose the removal of unbound analytes or reactants (col 8, 10, 38, and 56).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 38 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sosnowski et al in view of Butler (US 5,137,634) and further in view of Van Damme et al (US 6,225,131).

See above for teachings of Sosnowski et al.

Sosnowski et al differ from the instant invention in failing to teach the membrane supports a 100kPa pressure load and fails to teach the membrane is an aluminum oxide membrane. Sosnowski et al also fails to teach the aluminum oxide membrane is modified by membrane modifiers.

Butler et al disclose an aluminum oxide membrane. Butler et al also disclose that this membrane supports a 110 kPa pressure load (col 7). Butler et al disclose that this membrane is resistant to chemicals and heat and that this membrane is superior to organic membranes. Butler et al also disclose that this membrane is robust to resistant accidental damage (col 1, lines 17-34).

Van Damme et al disclose aluminum oxide membranes that have immobilized binding substances on the aluminum oxide membrane. Van Damme et al also teaches that this aluminum oxide membrane provides for an improved control over the liquid distribution over the surface of a substrate and allows for assays using various optical techniques (same as Sosnowski et al).

It would have been obvious to one of ordinary skill in the art to incorporate an aluminum oxide membrane as taught by Butler et al into the method of Sosnowski et al because Butler et al shows that this membrane is resistant to chemicals and heat and that this membrane is superior to organic membranes. Butler et al also disclose that this membrane is robust to resistant accidental damage.

Although Van Damme et al teaches that the binding substances are located within the pores, the whole membrane of Van Damme et al is comprised of aluminum oxides and one of ordinary skill in the art would be able to immobilize the binding substances on the surface of the membrane that is not within the pores. Therefore, it would have been obvious to one of ordinary skill in the art to immobilize binding substances (membrane modifiers) as taught by Van Damme et al on the surface of the modified membrane of Sosnowski et al.

7. Claims 39 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sosnowski et al in view of Lee et al. (US 6,180,418).

See above for teachings of Sosnowski et al.

Sosnowski et al differ from the instant invention in failing to teach the pore density of at least $10^{15}/\text{m}^2$. Sosnowski et al also fails to teach the membrane is coated with a biotin-polyethylene-glycol (PEG) using a polyethyleneimine layer.

Lee et al disclose coating a surface with PEG using a polyethyleneimine (PEI) layer. Lee et al disclose that this coating will be advantageous to limit nonspecific adsorption by coating the substrate with an agent that minimizes nonspecific adhesion.

It would have been obvious to one of ordinary skill in the art to coat the membrane of Sosnowski et al with PEG and PEI as taught by Lee et al because Lee et al shows that this coating will be advantageous to limit nonspecific adsorption by coating the substrate with an agent that minimizes nonspecific adhesion.

With respect to the pore density recited in the instant claims, the optimum pore density can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation."

Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ."
Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective

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variable in a known process is ordinarily within the skill of the art.” Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

Response to Arguments

8. Applicant's arguments filed January 25, 2005 have been fully considered but they are not persuasive.

Applicant argues that the '380 patent does not teach flowing the analytes to and through the membrane. This is not found persuasive because the argument is not relevant. The instantly recited claims are directed to the test solution flowing to and through the membrane wherein the membrane has pores that prevent the analyte from passing into or through the membrane and Sosnowski et al specifically teaches this feature (see above rejection). Applicant argues that Sosnowski et al teaches a device which electronically delivers reagents and reactants with a minimal use of fluidics. This is not found persuasive because as stated by Sosnowski et al the delivery is minimal. Thus Sosnowski et al teaches the use of fluidics, although it might be to a small degree. Further, Sosnowski et al teaches that a sample solution is applied to the device containing the permeation membrane and that the membrane is selective to not allow the larger binding entities, reactant and analytes to pass through. However, Sosnowski et al teaches that other constituents of the solutions are able to permeate the membrane. According to the Webster's II New Riverside University Dictionary 1994 edition. The term “permeate” is defined as to flow to pass through the openings or interstices of (e.g. a membrane). Therefore, Sosnowski et al teaches that the test solution flows through the membrane. Applicant further argues that Sosnowski does not

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teach a membrane designed specifically to separate molecules from solvent using solvent flow where the solvent is free to pass through and exit the membrane. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., exits the membrane) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, Sosnowski et al disclose that the membrane can be between a void space and the electrode (see for example, Fig. 6).

Applicant argues that since the rejection of Sosnowski et al has been removed, the rejections concerning the secondary and tertiary references are also removed. This is not found persuasive because as stated above the Sosnowski et al reference reads on the instantly recited claims and therefore, the combination with the secondary and tertiary references are maintained.

Conclusion

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts
Examiner
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April 7, 2005